UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA and
THE STATE OF CALIFORNIA, *ex rel.*
STEVEN HIGGINS,

Plaintiffs,

v.

BOSTON SCIENTIFIC CORP.,

Defendant.

Case No. 11-cv-2453 (JNE/SER)
ORDER

Relator Steven Higgins has sued Defendant Boston Scientific Corporation *qui tam* under the False Claims Act and a state analog. He alleges, among other things, that Boston Scientific misled the FDA by fraudulent omission. Boston Scientific moves to dismiss Higgins's Second Amended Complaint, Dkt. No. 98, "the Complaint," under Federal Rule of Civil Procedure 9(b), for pleading that alleged fraud without particularity. Dkt. No. 103, "the Motion." To the contrary, Higgins has particularly pled fraud in how Boston Scientific allegedly misled the FDA. The Complaint alleges details about, for example, how Boston Scientific's regulatory staff omitted amendments to Premarket Approval Supplements ("Supplements") for implantable defibrillators and how that omission misled the FDA's product-review team into approving those devices.[1] For this

[1] A Premarket Approval Supplement is "the submission required for a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA[, or, premarket approval]." *PMA Supplements and Amendments*, FDA (Nov. 14, 2017), https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm050467.htm. Boston Scientific filed Supplements for its implantable defibrillators here because those devices

reason, elaborated below, the Court DENIES the Motion.

To plead fraud by omission with particularity, a complaint must allege how a particular statement was made misleading by fraudulent omission.

"In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Rule 9(b). Particularity gives the defendant "sufficient notice of the allegations" so to prepare "an effective defense." *Streambend Props. II, LLC v. Ivy Tower Minneapolis, LLC*, 781 F.3d 1003, 1010 (8th Cir. 2015); *see* Order 20, Dkt. No. 97. One fraud alleged here is that Boston Scientific misled the FDA's product-review team by omitting required amendments to its submissions.

To plead fraud by omission with particularity, a complaint must detail the statement made misleading by the omission, the omission, and how the omission makes the statement misleading. *See* Order 20. For the statement, the complaint must allege its "who, what, where, when, and how." *Streambend Props*, 781 F.3d at 1010. For the omission, the complaint must allege a representative example. Order 20. This example should illustrate the information omitted, the defendant's knowledge about that information, and the defendant's duty to disclose that information. And the complaint must allege how the statement's reader would have been misled reading the statement without the omitted information. By alleging these particular facts, the Complaint here meets Rule 9(b) for the alleged fraud by omission discussed below.

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were a change to an earlier generation of defibrillators that already had premarket approval.

The Complaint pleads fraud by omission with particularity because it alleges how pending Supplements' statements about device safety and effectiveness were made misleading by omitted amendments to those Supplements about device defects.

During the approval process for Boston Scientific's implantable defibrillators, the Corporation's regulatory employees submitted statements to the FDA, statements in the December 2007 Supplements. Compl. ¶ 235. The Complaint names the employees who allegedly would have interacted with the FDA about these Supplements. *Id.* ¶ 238. Allegedly, some of these employees managed the implantable defibrillators' approval process by interacting with an FDA product-review team. *Id.* ¶ 230. In the Supplements submitted to this product-review team, Boston Scientific's regulatory employees allegedly stated to the team that the implantable defibrillators were safe and effective. *Id.* ¶ 236. These statements would have been required for the May 2008 FDA approval, which allowed Boston Scientific to sell the implantable defibrillators in the United States. *Id.* ¶ 249.

But between December 2007 and May 2008, Boston Scientific had launched the implantable defibrillators in Europe. *Id.* ¶ 241. There, forty were allegedly implanted starting in February 2008. *Id.* Boston Scientific allegedly received reports of fatal defects. *Id.* ¶¶ 242, 247. Responding to these reports, the Corporation allegedly dispatched a named engineer to find a workaround. *Id.* ¶¶ 103, 138.

Once the Supplements were pending before the FDA's product-review team—as was the case during the European launch—Boston Scientific had to amend them as "new safety and effectiveness information learned about the device" arose. *Id.* ¶ 44 (quoting

duty from 21 C.F.R. § 814.20(e) (2017)[2]). Allegedly, though, its regulatory employees omitted amending the Supplements despite the European launch having created new safety and effectiveness information. *Id.* ¶ 245. The product-review team would have had only Boston Scientific's statements of safety and effectiveness and supporting documents. Allegedly, this selective presentation would have misled the product-review team because that team relied on Boston Scientific, the devices' sponsor, to bring data on device risks to its attention. *Id.* ¶ 245.

This allegation has enough details to meet Rule 9(b) particularity. In the December 2007 Supplements, some of Boston Scientific's named regulatory employees allegedly made statements vouching for the implantable defibrillators' safety and effectiveness, statements made to the FDA's product-review team. The Court may reasonably infer these statements from the Supplements because, to proceed to approval, the Supplements had to include affirmative statements for the implantable defibrillators' safety and effectiveness. With the Supplements pending before the product-review team, Boston Scientific had to amend them to alert that team about defects allegedly manifesting in the European launch. Allegedly, though, Boston Scientific never amended the Supplements despite knowing about those defects. Because the product-review team allegedly relied on Boston Scientific to feed it a complete data set about the implantable defibrillators' risk, the omitted amendments would have made misleading the

[2] "The applicant shall periodically update its pending application with new safety and effectiveness information learned about the device from ongoing or completed studies that may reasonably affect an evaluation of the safety or effectiveness of the device. . . ." 21 C.F.R. § 814.20(e) (2017).

Supplement statements affirming those devices' safety and effectiveness. Because particularity is met, the MOTION is DENIED.

Conclusion

Therefore, based on the files, records, and proceedings herein, IT IS ORDERED THAT:

1. Defendant Boston Scientific Corporation's Motion to Dismiss [Dkt. No. 103] is DENIED.

2. Relator Steven Higgins's Motion to Continue Hearing [Dkt. No. 112] on the above motion is DENIED as moot.

Dated: December 13, 2017

s/ Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge